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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,034	11/21/2003	Alex T. Roth	HRT0165C1	3160
27777	7590	08/17/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/719,034

Applicant(s)

ROTH, ALEX T.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-16 and 18-20 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-5, 7-16 and 18-20 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/22/2004.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

***Status of the Claims***

Applicant's response filed on June 28, 2004 notes that preliminary amendment filed on November 21, 2003 was listed in the record but the substance of the amendment was not officially entered into the application. Accordingly, claims 21-42 were cancelled and only claims 1-20 were available for review by the Examiner. Examiner agrees with applicant that the outstanding restriction is moot. Therefor the restriction requirement dated April 27, 2004 has been vacated. No further response is required by applicant. The instance office action will treat claims 1-20 on their merits.

Applicant is put on notice that the original claim set includes claims 1-5,7-16,18-20. It appears there are no claims 6 and 17. Therefor the instant office action will reflect only claims 1-5 and 7-16,18-20.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3,4,5,8,11,12,13,14 are rejected under 35 U.S.C. 102(b) as being anticipated by Adair (4878485).

Adair discloses an assembly for visualization and access within a body cavity comprising:

a sleeve 30 having a distal end 32, a proximal end 34, and a lumen therebetween;

a scope 10 having a shaft with a distal end 12 and a proximal end 26, the shaft being slidably positionable in the lumen, a channel 16 extending longitudinally through the shaft, and a lens 12 in the channel near the distal end,

a transparent bulb 32 disposed at the distal end of the shaft outside of the channel and optically aligned with the lens.

Claim 3, see bulb 32 attached to sheath 30 of Adair.

Claim 4, see rigid bulb of Adair.

Claim 5, see column 5, lines 1+ of Adair.

Claim 8, the claim is interpreted as the assembly having a predetermined length.

Claim 11, see sleeve 30 of Adair.

Claim 12, see rejection to claim 1 supra.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5,7-16,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (4878485) or Mackin in view of Wakabayashi (5176649).

Adair and Mackin disclose an assembly for visualization and access within a body cavity comprising:

a scope (10,5) having a shaft (10,6) with a distal end and a proximal end, a channel (16,11) extending longitudinally through the shaft, and a lens (12,12) in the channel near the distal end,

a transparent bulb (32,7) mounted to an elongated a sheath/shaft (30,6) having a distal end, a proximal end, and a lumen therebetween and the bulb is disposed at the distal end of the shaft outside of the channel and optically aligned with the lens.

Adair and Mackin do not disclose the combination of a sleeve and the scope wherein the combination would result in the shaft being slidably positionable in the lumen. Wakabayashi teaches the use of a sleeve to aid in the placement of endoscopic type devices thereby eliminating the need for multiple punctures to the tissue. To use a trocar sleeve in combination with the scopes of Adair and Mackin to provide a reusable tissue port would have been obvious from the teachings of Wakabayashi.

Claim 2, see bulb 7 attached to shaft 6 of Mackin.

Claim 3, see bulb 32 attached to sheath 30 of Adair.

Claim 4, see rigid bulb of Adair.

Claim 5, see column 5, lines 1+ of Adair.

Claim 7, see bulb of Mackin.

Claim 8, the claim is interpreted as the assembly having a predetermined length.

Claim 9, if not inherent, it appears that the length of the assembly of each of Mackin and Adair is at least 15 cm.

Claim 10, see bulb and inflation lumen in fluid communication with bulb of Mackin.

Claim 11, the sleeve of Wakabayashi may be polymer or metal.

Claim 12, see rejection to claim 1 supra.

Claim 13, see bulb of Adair.

Claim 14, see column 5, lines 1+ of Adair.

Claim 15, see bulb of Mackin.

Claim 16, see bulb of Mackin.

Claim 18, see combination of Wakabayshi and Mackin/Adair.

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair or Mackin modified by Wakabayshi further in view of Marks (5108420).

Adair and Mackin disclose an assembly for visualization and access within a body cavity a scope (10,5) having a shaft (10,6) with a distal end and a proximal end, a channel (16,11) extending longitudinally through the shaft, and a lens (12,12) in the channel near the distal end,


a transparent bulb (32,7) mounted to an elongated a sheath/shaft (30,6) having a distal end, a proximal end, and a lumen therebetween and the bulb is disposed at the distal end of the shaft outside of the channel and optically aligned with the lens.

Adair and Mackin do not disclose the combination of a sleeve, the scope and a septal defect closure device. Wakabayashi teaches the use of a sleeve to aid in the placement of endoscopic type devices thereby eliminating the need for multiple punctures to the tissue. To use a trocar sleeve in combination with the scopes of Adair and Mackin to provide a reusable tissue port would have been obvious from the teachings of Wakabayashi. And Marks teaches a septal repair device that has a configuration that allows it to be positionable through a lumen of a sleeve as shown, for example, by Wakabayashi. To use the combination of a sleeve, scope and septal repair device to perform corrective surgery to the heart wall would have been obvious to one with ordinary skill in the art as an obvious combination of surgical tools/devices based on surgical considerations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
August 13, 2004